RESEARCH PAPER

Trends in nicotine yield in smoke and its relationship with design characteristics among popular US cigarette brands, 1997–2005

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Objectives: To determine whether nicotine yields in the smoke of cigarettes would show an overall increase over time or an increasing trend limited to any particular market category (eg, full flavour vs light, medium (mild) or ultralight; mentholated vs non-mentholated), manufacturer, or brand family or brand style, and whether nicotine yields in smoke would be associated with measurable trends in cigarette design.
Methods: Machine-based measures of nicotine yield in smoke and measures of cigarette design features related to nicotine delivery (ventilation, nicotine content in the tobacco rod and number of puffs), as well as market category descriptors, were obtained from annual reports filed with the Massachusetts Department of Public by tobacco manufacturers for 1997–2005. Trends in nicotine yield and its relationship with design features and market parameters were analysed with multilevel mixed-effects regression modelling procedures.
Results: A statistically significant trend was confirmed in increased nicotine yield, of 0.019 (1.1%) mg/cig/year over the period 1997–2005 and 0.029 (1.6%) mg/cig/year over the period 1998–2005. The increasing trend was observed in all major market categories (mentholated vs non-mentholated, and full flavour vs light, medium (mild) or ultralight). Nicotine yield in smoke was positively associated with nicotine concentration in the tobacco and number of puffs per cigarette, both of which showed increasing trends during the study period.
Conclusions: This study confirms increased machine-measured levels of nicotine, the addictive agent in cigarettes, in smoke, to be a result of increased nicotine in the tobacco rod and other design modifications.

The 1981 US Surgeon General report, *The health consequences of smoking: the changing cigarette*, highlighted the need to "continue to monitor the changing cigarette to ensure that when new cigarette products appear they do not bring with them new hazards to health".[1] Nicotine, as the agent primarily responsible for addiction, has been identified as a parameter of unique importance in assessment of the changing cigarette.[2] Recent findings by the United States District Court for the District of Columbia underscore the need for continued surveillance of the delivery of nicotine.[3] In the District Court's 2006 ruling, Judge Kessler concluded that tobacco companies "can and do control the level of nicotine delivered in order to create and sustain addiction", and further that the "goal to ensure that their products deliver sufficient nicotine to create and sustain addiction influences their selection and combination of design parameters".[3]

The US Federal Trade Commission (FTC) began publishing standardised machine-generated measures of nicotine yield in smoke for US cigarettes since 1967.[4] Machine-generated measures remain the most widely available methods for comparison of smoke generation across brand families and brand styles irrespective of individual smoking behaviour. However, smokers compensate for increasing smoke yield.[5 6] It is well established that smokers tend to take larger puffs or otherwise increase smoke intake when they switch to a lower yield cigarette, and that these shifts in behaviour compensate for nicotine exposure.[7–11]

Machine-based measures of nicotine yield may be instructive to the extent that they reflect the ease with which a smoker can extract nicotine and achieve or sustain a given level of nicotine exposure.[12] This can be enhanced through an increased availability of nicotine in the unburned rod, reduced cigarette burn rate (resulting in more puffs taken per cigarette) or a higher rate of transfer of nicotine from the tobacco rod to the smoke.

Since 1997, Massachusetts regulations require an annual report to be filed with the Massachusetts Department of Public Health (MDPH) by all manufacturers of cigarettes sold in Massachusetts.[13] The reported data include machine-based measures of nicotine yield, as well as measures of cigarette design related to nicotine delivery (ventilation, nicotine content in the tobacco rod and number of puffs). The Tobacco Research Program at the Harvard School of Public Health obtained from MDPH a complete set of the available Massachusetts brand-specific data from 1997 to 2005. The objectives of this study were to examine trends in nicotine yield in smoke and to evaluate these trends with respect to data available pertaining to market category and cigarette design. We sought to determine (a) whether machine-generated data reflect an increase over time in nicotine yield; (b) whether an increase in nicotine yield would be limited to any particular market category (eg, full flavour vs light, medium (mild) or ultralight; mentholated vs non-mentholated), manufacturer, or brand family or brand style; and (c) whether an increase in nicotine yield would be associated with measurable trends in cigarette design.

Abbreviations: FTC, Federal Trade Commission; ISO, International Standard Organization; MA, Massachusetts; MDPH, Massachusetts Department of Public Health

METHODS

Description of data

Data were received from MDPH for 1997–2005. For the majority of brands in each year, Massachusetts regulations require manufacturers to report the most recent available FTC or International Standards Organisation (ISO) machine-generated smoke yield of nicotine. The FTC/ISO methods were developed to facilitate comparison between cigarette brand families and brand styles under a uniform set of smoking conditions.[13] Brand-specific market categories are also reported for each cigarette.

Brand families (eg, Marlboro, Camel) with a significant market share (defined as >5% in 1997, and as >3% in all subsequent years) were subject to expanded reporting requirements. The regulations also permit MDPH to select a small number of additional brand styles (between 3 and 15 per manufacturer, based on the manufacturer's overall market share) in each year, which were then subject to expanded reporting requirements. The expanded MDPH reporting requirements include measures of nicotine yield in smoke generated by a smoking machine, according to a more intensive set of parameters commonly referred to as the Massachusetts (MA) regimen. These parameters are comprised of a 45 ml puff volume, 30 s interval between puffs, 2 s puff duration, 50% blocked ventilation holes and cigarette smoked to 23 mm butt length on an unfiltered cigarette, or overwrap plus 3 mm on a filtered cigarette. The expanded reporting requirements also include the number of puffs generated per cigarette, based on the MA smoking regimen; nicotine content in the unburned tobacco per cigarette (mg/cig) and nicotine concentration (mg nicotine per gram tobacco; the latter available only from 1998 onwards); per cent filter ventilation; FTC/ISO nicotine yield in smoke; and a classification of yield (high/medium/low) defined by the MA regulations. No other cigarette design parameters are reported in accordance with the current MA reporting requirements. Methods for obtaining these measures are described in the MDPH regulations.[13] Laboratory measurements were made and submitted by the manufacturers for their own brands, as well as for the samples of other companies' brands, to ascertain interlaboratory reliability as of 1998. Machine-generated data on smoking, based on the MA smoking regimen and not on the FTC/ISO method, are analysed in this report.

Coding of data

The scope of the analysis was limited to brands sold by the major manufacturers: Philip Morris (PM) USA; Reynolds American (categorised separately as RJ Reynolds and Brown & Williamson); and Lorillard Tobacco. The analysis was further limited to brand styles for which expanded data regarding design features and nicotine yield in smoke were available. All brand styles were coded according to market categories, including full flavour/light/medium (mild)/ultralight; mentholated/non-mentholated; filtered/non-filtered; length (70/72/85 (King)/100/120 mm); box (hard pack/soft pack/tin) candy- or exotic flavoured (eg, Crema, Dark Mint)/non-candy-flavoured. Brand styles were defined as packagings with unique combinations of these market categories (eg, Camel King Filter Tin Menthol 85). We calculated tobacco weight for each brand style by dividing nicotine content per cigarette by nicotine concentration per gram of tobacco. The nicotine yield in smoke was calculated per puff by dividing MA nicotine yield in smoke by the number of puffs per cigarette.

Complete data were available for all variables except market share classification, nicotine concentration in the tobacco rod and weight—for which at least 95% of the data were available. Reported data were checked against the original submissions from the manufacturers, and outliers were flagged for possible misclassification and corrected.

Statistical analysis

Temporal trends in nicotine yield in smoke

The trends in nicotine yield in smoke over time were tested using regression analysis, with nicotine yield per cigarette and nicotine yield per puff as dependent variables, and year as the independent variable. A multilevel mixed fixed-effects and random-effects regression model was used to account for the nested structure of brand styles grouped within brand families, which were in turn grouped within manufacturers.[14,15] Time (or the year of the sample) was treated as the fixed effect in this model.

A regression model of temporal trend in nicotine yield in smoke was constructed for the reported data. As the interlaboratory reliability in 1997, the first year of testing, was questionable, and owing to the relatively low number of brand styles sampled in 1997 (between one-half and one-third of the number of styles sampled in subsequent years), coupled with the lack of availability of brand-specific data on nicotine concentration (mg nicotine per gram tobacco) and calculated tobacco weight, the primary analyses were conducted on the data reported from 1998 to 2005. Descriptive analyses included the 1997 data, as well as an additional regression model performed for comparative purposes.

In order to assess changes in nicotine yield in smoke, the nicotine yields of brand styles reported in the baseline year, 1998, were compared with those of new brand styles introduced in subsequent years. The hypothesis that the nicotine yields in smoke of new cigarette brand families and brand styles entering the market differed from those of brand families and brand styles existing in the market in 1998 was tested using regression analysis, including time frame of entry into the market (1998 vs 1999–2005) as an independent fixed-effect variable.

Likelihood ratio tests of models in the presence or absence of random effects were used to determine the statistical significance of those effects. For example, differences in nicotine yields in smoke between manufacturers were tested for statistical significance by comparing multilevel models with and without the manufacturer random effect. Statistically significant differences in the temporal trends in nicotine yields between manufacturers, brand families and brand styles were tested by comparing models with and without the time included as a variable within the respective level.

A subset analysis of temporal trends in nicotine yield among Marlboro brand cigarettes was performed, including additional data for this brand obtained from MAPH for the year 2006, in order to assess a response by PM USA to a reported trend by MDPH of increased nicotine yield in smoke for Marlboro.[16]

Potential determinants of nicotine yield in smoke

Potential correlates of nicotine yield in smoke consist of market categories (full flavour vs light, medium (mild) or ultralight; mentholated vs non-mentholated; filtered vs non-filtered; length $\leqslant$100 vs >100 mm; candy-flavoured or exotic flavoured (eg, Crema, Dark Mint) vs non-candy flavoured); and physical measures of cigarette design or smoke yield (number of puffs per cigarette; mg nicotine content in the unburned tobacco per cigarette and nicotine concentration (mg nicotine per gram tobacco); tobacco weight per cigarette; and per cent filter ventilation. Nicotine yield in smoke is generated by burning tobacco and drawing smoke through the tobacco column according to a consistent set of conditions as specified by the MA method. As a result, a change in nicotine yield in smoke should reflect physical design differences in the product, such as the amount of burned tobacco, the amount and concentration of nicotine in the tobacco, the burn rate of the cigarette between puffs, degree of ventilation or other measures.

Table 1 Frequencies of reported cigarette brand families and brand styles

	1997	1998	1999	2000	2001	2002	2003	2004	2005
Manufacturer									
Brown & Williamson	19	45	44	44	28	27	17	NA	NA
Lorillard	13	18	17	21	22	22	22	21	21
Philip Morris	20	49	57	58	59	64	61	63	64
RJ Reynolds	33	79	82	93	108	101	93	113	87
Market category									
Mentholated	29	72	82	82	80	74	78	85	59
Non-mentholated	56	119	118	134	137	140	115	112	113
Full flavour	34	77	74	79	81	81	68	69	74
Light	35	70	73	82	88	87	79	83	67
Medium/mild	6	10	10	11	9	11	12	16	3
Ultralight	10	34	43	44	39	35	34	29	28
Filtered	83	185	195	211	212	208	188	194	170
Non-filtered	2	6	5	5	5	6	5	3	2
Total									
Brand families	5	22	23	23	21	18	19	16	18
Brand styles	85	191	200	216	217	214	193	197	172
⩾3% market share per brand family									
Brand families	NR	9	9	9	8	7	7	7	6
Brand styles	NR	162	167	181	180	175	152	163	136

NA, not applicable after Brown & Williamson's acquisition by RJ Reynolds; NR, not reported.

Bivariate and multivariate regression analyses were performed to determine the relationships between nicotine yield in smoke and each of the market categories and design features. Multilevel modelling was performed first with nicotine yield in smoke as the dependent variable, and with a single market category or design feature as the independent fixed-effect variable. Statistically significant predictor variables from these analyses were then entered as fixed-effect independent variables in a stepwise backwards multivariate regression analysis. Brand style, brand family and manufacturer were treated as random effects in the multilevel models. The market category filtered vs non-filtered was not included in multivariate analyses, as filtered products are the predominant cigarettes on the market and comprise 98% of the sample.

Certain predictor variables (eg, nicotine content per cigarette and nicotine concentration in the tobacco rod) might be highly intercorrelated, resulting in the possibility that variance not related to the prediction of the dependent variable would be suppressed by one of the intercorrelated predictor variables.[17 18] In these cases, the significant regression coefficients of the two variables might not reflect the direct contributions of those variables as predictors. Therefore, several multiple regression models were examined to explore the contributions of the predictor variables. Inclusion of one or both variables in the selected model was determined on the basis of changes in the standard errors, where evidence of the ''suppressor variable'' effect was observed.

A full model of temporal and design factors related to nicotine yield in smoke was identified using multilevel regression analysis, including time as well as the remaining statistically significant predictors among the market category and design features. Multilevel mixed regression models were also used to analyse temporal changes among the market categories and design features that were associated with nicotine yield in smoke. Market category and design features that were found to be associated with nicotine yield in smoke and that also displayed a corresponding temporal trend were modelled using the same multilevel structure, in order to identify any significant predictors of these parameters.

Statistical analyses were performed using Stata Statistical Software V.9.

RESULTS

Description of sample

Brand families and brand styles included in the analysis are summarised in table 1. The number of sampled brand styles from 1998 to 2005 ranged between 172 and 217 and peaked during 2000–2. The much lower relative number of brand styles in 1997 (85) reflects the different MA regulatory requirements in 1997 (>5% rather than 3% market share).

The number of brand families meeting the subsequent 3% market share threshold reduced gradually from 22 to 18 between 1998 and 2005, while the number of brand styles within brand families increased from year to year, possibly reflecting a consolidation of brand families. In each year, brand styles from brand families with <3% market share comprised 15–21% of the overall sample. RJ Reynolds brand families and brand styles for 2004–5 reflect the acquisition of Brown & Williamson, specifically the addition of Kool, which decreased to 3% market share only in 2004.

Approximately 38% of the overall sample were full flavour cigarettes, and 39% were light cigarettes, while 5% were medium/mild brand styles and the remaining 18% were ultralights. From 1998 to 2004, the percentage of full flavour brand styles (40–35%) and ultralight brand styles (18–15%) trended downwards, whereas that of light cigarettes trended upwards (37–42%) during this period. In 2005, however, this trend was reversed, with 43% full flavour versus 39% light cigarettes, and only 2% medium/mild. In all, 38% of the overall study sample was mentholated, with no apparent trend and relatively little year-to-year variation (34–43%). A similar proportion of brand styles were mentholated within each of the categories full flavour (42%), light (38%) and medium (mild) (45%), whereas in the ultralight category a much lower proportion (26%) was mentholated. An extremely small percentage (1–3%) of the total year-to-year sample was non-filter, consistent with the trend in the overall US cigarette market.

Temporal trends in nicotine yield in smoke

The fixed-effects multilevel model, with time as the only predictor variable, showed an increase in the nicotine yield in smoke of cigarettes at an overall rate of 0.019 mg/cig/year (95% CI 0.016 to 0.022) from 1997 to 2005 (or an overall rate of 0.029 mg/cig/year (95% CI 0.010 to 0.044) from 1998 to 2005;

Table 2 Bivariate and multivariate regression analyses of trend and determinants of nicotine yield (mg/cig) from 1998 to 2005

	Nicotine yield in smoke (mg/cig) Bivariate analyses*		Nicotine yield in smoke (mg/cig) multivariate analysis†		Market category and design time trends‡	
	ββ§ (95% CI)	p Value	ββ§ (95% CI)	p Value	ββ¶ (95% CI)	p Value
Time trend (years)						
All manufacturers	0.029 (0.010 to 0.044)	0.003	0.009 (0.006 to 0.011)	<0.001		
Brown & Williamson	0.059 (0.049 to 0.069)	<0.001				
Lorillard	0.030 (0.187 to 0.041)	<0.001				
Philip Morris	0.011 (0.006 to 0.015)	<0.001				
RJ Reynolds	0.020 (0.016 to 0.024)	<0.001				
Market category						
Length (⩾100 mm)	0.097 (0.005 to 0.190)	0.038	–	NS		NS
Mentholated vs non-mentholated	–0.043 (–0.137 to 0.051)	0.367	–	NS		NS
Candy-flavoured vs non-flavoured	–0.099 (–0.194 to –0.004)	0.041	–	NS		NS
Full flavour vs non-full flavour	0.348 (0.300 to 0.395)	<0.001	0.187 (0.155 to 0.219)	<0.001	0.006 (0.004 to 0.009)	<0.001
Filtered vs non-filtered	–0.092 (–0.221 to 0.036)	0.160	–	NS	0.002 (0.001 to 0.003)	0.001
Design feature						
Nicotine concentration (mg/g)	0.037 (0.032 to 0.042)	<0.001	0.030 (0.025 to 0.034)	<0.001	0.177 (0.147 to 0.207)	<0.001
Nicotine (mg) per cigarette	0.061 (0.055 to 0.067)	<0.001		NS	0.135 (0.110 to 0.161)	<0.001
Puffs per cigarette	0.091 (0.079 to 0.103)	<0.001	0.106 (0.098 to 0.113)	<0.001	0.048 (0.035 to 0.060)	<0.001
Percentage filter ventilation	–0.013 (–0.014 to –0.011)	<0.001	–0.014 (–0.015 to –0.013)	<0.001		NS
Weight (g)	1.563 (1.325 to 1.801)	<0.001		NS		NS

cig, cigarette; NS, not significant.
*Each individual multilevel regression model consists of the Massachusetts (MA) regimen-measured nicotine yield as the dependent variable, and one market category, design feature or time (in years) as the independent variable.
†Results are given for the multilevel mixed-effects multiple regression model of MA regimen-measured nicotine yield in smoke, including all significant parameters.
‡Each individual multilevel regression model consists of one market category or design feature as the dependent variable, and time as the independent variable.
§ β-coefficients represent mg increase in nicotine yield in smoke per unit change of each parameter per year.
¶ β-coefficients represent unit change of each parameter per year.

table 2). The rate of increase in total nicotine yield differed between manufacturers (likelihood ratio test $p<0.001$). Time was therefore treated both as a fixed-effect and as a random-effect variable within the manufacturer level in the above models. The mean fitted nicotine yield in smoke in each model was 1.79 mg/cig (not shown). The average annual rate of increase observed was thus 1.1% from 1997 to 2005, or 1.6%/year from 1998 to 2005. The cumulative increase in nicotine yield was thus 8.5% from 1997 to 2005 or 11.3% from 1998 to 2005. The increasing trend in nicotine yield in smoke during this period was also observed on a per puff basis (0.0012 mg nicotine/puff/year, 95% CI 0.0009 to 0.0015; not shown).

The brand styles of all the four major manufacturers exhibited temporal trends of increased nicotine yield during 1998–2005. Rates of increase in nicotine yield in this period for each of the four manufacturers are shown in table 2.

No statistically significant difference was observed in temporal trends in nicotine yield in smoke between brand families (likelihood ratio test, $p = 0.466$) or between brand styles (likelihood ratio test, $p = 0.299$; analysis restricted to brand styles with ⩾3 observations). Brand styles introduced in 1999–2005 did not exhibit differences in nicotine yields in smoke on the average, compared with brand styles reported in 1998 ($p = 0.349$; not shown).

Relationship of market categories with nicotine yield in smoke

Results of bivariate analyses of nicotine yield in smoke and market categories and design features are shown in table 2. Statistically significant associations were observed between nicotine yield in smoke and market categories >100 mm in length ($p = 0.038$), non-candy flavoured ($p = 0.041$) and full flavour ($p<0.001$) cigarettes, but were not observed with mentholated ($p = 0.367$) or filtered ($p = 0.160$) categories.

Mean yearly nicotine yields in smoke for all brand styles within selected market categories are shown in table 3. Increases in nicotine yield in smoke were apparent from 1998 to 2005 in both menthol categories (mentholated and non-mentholated), as well as within full flavour, light, medium (mild) and ultralight categories.

Relationship of product design features with nicotine yield in smoke

Bivariate analyses of nicotine yield in smoke and design features demonstrated statistically significant associations with nicotine yield per cigarette, nicotine concentration in the tobacco rod, number of puffs per cigarette, per cent filter ventilation and tobacco weight ($p<0.001$ for all; table 2).

Table 3 Nicotine yield in smoke (mean mg/cig (SD)) based on the Massachusetts smoking regimen for all cigarette brand styles and major market categories in 1997–2005

	1997	1998	1999	2000	2001	2002	2003	2004	2005
All styles									
Non-mentholated	1.64 (0.37)	1.62 (0.46)	1.65 (0.48)	1.67 (0.51)	1.80 (0.51)	1.83 (0.53)	1.85(0.56)	1.91 (0.62)	1.88 (0.62)
Mentholated	1.84 (0.49)	1.77 (0.44)	1.71 (0.46)	1.83 (0.47)	1.84 (0.45)	1.80 (0.47)	1.84 (0.50)	1.90 (0.47)	1.95 (0.47)
Total	1.70 (0.42)	1.68 (0.45)	1.68 (0.47)	1.73 (0.50)	1.82 (0.49)	1.82 (0.51)	1.84 (0.53)	1.91 (0.56)	1.90 (0.57)
Full flavour									
Non-mentholated	1.94 (0.25)	2.02 (0.35)	2.08 (0.38)	2.15 (0.44)	2.28 (0.40)	2.28 (0.53)	2.32 (0.55)	2.42 (0.68)	2.28 (0.65)
Mentholated	2.21 (0.47)	2.08 (0.36)	2.12 (0.33)	2.22 (0.38)	2.19 (0.33)	2.04 (0.50)	2.23 (0.42)	2.31 (0.43)	2.24 (0.42)
Total	2.04 (0.37)	2.04 (0.36)	2.10 (0.36)	2.18 (0.41)	2.24 (0.37)	2.19 (0.53)	2.28 (0.50)	2.37 (0.58)	2.26 (0.57)
Light									
Non-mentholated	1.51 (0.24)	1.56 (0.25)	1.61 (0.23)	1.64 (0.24)	1.71 (0.27)	1.70 (0.18)	1.73 (0.24)	1.75 (0.19)	1.78 (0.29)
Mentholated	1.60 (0.20)	1.56 (0.27)	1.54 (0.21)	1.58 (0.20)	1.67 (0.24)	1.67 (0.34)	1.68 (0.31)	1.69 (0.31)	1.73 (0.29)
Total	1.54 (0.23)	1.56 (0.25)	1.58 (0.22)	1.62 (0.23)	1.70 (0.26)	1.69 (0.24)	1.71 (0.27)	1.72 (0.24)	1.76 (0.29)
Medium/mild									
Non-mentholated	1.68 (0.26)	1.62 (0.33)	1.70 (0.31)	1.73 (0.36)	1.78 (0.28)	2.01 (0.62)	2.22 (0.56)	2.26 (0.66)	3.40 (0.00)
Mentholated	NA	1.62 (0.05)	1.68 (0.09)	1.81 (0.12)	1.93 (0.21)	2.05 (0.31)	1.88 (0.24)	1.96 (0.14)	1.97 (0.34)
Total	1.68 (0.26)	1.62 (0.25)	1.69 (0.23)	1.76 (0.27)	1.83 (0.26)	2.02 (0.51)	2.02 (0.42)	2.05 (0.39)	2.45 (0.86)
Ultralight									
Non-mentholated	1.13 (0.16)	1.11 (0.30)	1.10 (0.27)	1.11 (0.29)	1.18 (0.31)	1.24 (0.16)	1.20 (0.16)	1.23 (0.14)	1.23 (0.20)
Mentholated	1.11 (0.05)	1.12 (0.17)	1.12 (0.21)	1.20 (0.19)	1.22 (0.27)	1.23 (0.15)	1.21 (0.33)	1.30 (0.13)	1.24 (0.14)
Total	1.12 (0.15)	1.11 (0.28)	1.10 (0.25)	1.13 (0.27)	1.19 (0.29)	1.24 (0.15)	1.21 (0.22)	1.25 (0.14)	1.23 (0.19)

NA, no observation.

Modelled predictors of nicotine yield in smoke

Table 2 displays the results of the best-fitting multivariate regression analysis model. The highly intercorrelated nature of nicotine concentration in the tobacco rod and nicotine content per cigarette, and the direct relationship between these two variables and tobacco weight results in the ''suppressor variable'' effect described above. Inclusion of these variables in the model was therefore determined on the basis of changes in SE. The cigarette design features significantly associated with increased nicotine yield in smoke were nicotine concentration, number of puffs per cigarette and per cent filter ventilation. Cigarette market category (full flavour vs light/ultralight/medium (mild)) was associated with increased nicotine yield in smoke (0.187 mg/cig; 95% CI 0.155 to 0.219), although the year-to-year rate of change between these categories reported was small. No statistically significant difference was observed in nicotine yield in smoke on comparing candy-flavoured or exotic-flavoured products (which increased from 1 brand style in 1999 to 31 brand styles in 2004) with non-candy flavoured products ($p = 0.198$; not shown).

The overall rate of increase over time in nicotine yield, controlling for significant market category (full flavoured vs light or ultralight) and the above cigarette design features, was 0.009 mg/year (95% CI 0.006 to 0.011). This suggests that these market and design parameters account for some but not all of the increase in nicotine yield in smoke. The results were similar when limiting the analysis to cigarette brand styles with $\geqslant$3% market share (not shown).

Temporal changes in cigarette design features and market categories

Mean values and SE of nicotine yield in smoke; market categories length, full flavour/non-full flavour, mentholated/non-mentholated; and design features total nicotine, nicotine concentration, number of puffs, per cent filter ventilation and tobacco weight for all years in the study are provided in table 4.

Table 4 Massachusetts regimen smoking measures and cigarette design features and selected market categories during 1997–2005 (mean (SE))

Year	Nicotine yield (mg/cig)	Total nicotine (mg/cig)	Nicotine conc (mg/g)	Number of puffs	% filter ventilation	Proportion of full flavour brands*
1997	1.70 (0.05)	11.85 (0.20)		11.34 (0.15)	22.81 (1.70)	0.40 (0.05)
1998	1.68 (0.03)	12.56 (0.14)	17.13 (0.14)	11.83 (0.12)	27.39 (1.43)	0.40 (0.04)
1999	1.68 (0.03)	12.54 (0.14)	17.27 (0.13)	11.94 (0.12)	29.01 (1.46)	0.37 (0.03)
2000	1.73 (0.03)	13.22 (0.15)	18.26 (0.15)	11.89 (0.11)	29.09 (1.41)	0.37 (0.03)
2001	1.82 (0.03)	13.67 (0.16)	18.88 (0.18)	12.24 (0.12)	28.18 (1.34)	0.37 (0.03)
2002	1.82 (0.03)	13.56 (0.20)	18.59 (0.20)	12.28 (0.15)	27.51 (1.31)	0.38 (0.03)
2003	1.84 (0.04)	14.53 (0.19)	19.74 (0.16)	12.50 (0.15)	28.67(1.39)	0.35 (0.03)
2004	1.91 (0.04)	14.40 (0.19)	19.62 (0.16)	12.34 (0.14)	26.08 (1.24)	0.35 (0.03)
2005	1.90 (0.04)	13.93 (0.22)	18.71 (0.17)	12.43 (0.16)	25.36 (1.30)	0.43 (0.04)
Total	1.79 (0.01)	13.46 (0.06)	18.52 (0.06)	12.13 (0.05)	27.47 (0.47)	0.38 (0.01)

*Binomial exact computation of SE.

Results of mixed multilevel regression of temporal trends in cigarette design features are shown in table 2. From 1997 to 2005, the mean nicotine content per cigarette rose by 17%, from 11.85 to 13.93 mg/cig ($p<0.001$). The mean concentration of nicotine in the tobacco rod rose by 9%, from 17.13 mg/g in 1998 to 18.71 mg/g in 2005 ($p<0.001$; data for 1997 were not available). The mean number of puffs per cigarette rose by 10%, from 11.3 in 1997 to 12.4 puffs/cigarette in 2005 ($p<0.001$). The peak mean values for each of these three design features occurred in 2003 (14.53 mg/cig nicotine; 19.73 mg/g nicotine; 12.5 puffs/cig). The yearly rate of change of filtered vs non-filtered brand styles was statistically significant but negligibly small ($p = 0.001$). The mean filter ventilation fluctuated in a tight range of 26–29% between 1998 and 2005, with lower values in 1997 (23%) and 2005 (25%), respectively ($p = 0.828$). The mean tobacco weight remained essentially constant from year to year, at 0.7 g ($p = 0.105$; 1998–2005, data for 1997 not available). Full-flavoured brands showed a statistically significant but very small increase from 1998 to 2005 ($p<0.001$). No change over time was observed in filter ventilation ($p = 0.752$), length (model includes manufacturer and brand levels only; $p = 0.399$), mentholated ($p = 0.113$), or candy- or exotic-flavoured brands ($p = 0.865$).

Multivariate regression analysis of the number of puffs per cigarette (not shown) showed an increase with time ($p<0.001$), tobacco weight ($p<0.001$), nicotine concentration in the tobacco rod ($p = 0.027$), per cent ventilation ($p<0.001$), length >85 ($p<0.001$), full flavour ($p<0.001$) and non-mentholation ($p = 0.014$).

Comparisons within brand families and brand styles

As statistically significant differences in trends of nicotine yield in smoke were not reported between brand families or brand styles, examination of nicotine trends at these levels is exploratory. Among the brand families with ⩾50 observations, seven brand families showed a significant increase in nicotine yield in smoke (Camel, Doral, GPC, Kool, Marlboro, Newport, Salem), whereas two brand families (Basic, Winston) showed no significant increase (table 5). Among the brand families that showed increased nicotine yield in smoke, increasing trends in number of puffs, nicotine content per cigarette and nicotine concentration in the tobacco rod were observed in Camel, Doral and Newport cigarettes. Increasing trends in nicotine content and nicotine concentration, but not in the number of puffs, were observed in Kool and Salem brand family cigarettes. Increasing trends in the number of puffs, but not in nicotine content measures, were observed for GPC. No trends were observed in measures of any of these design features for Marlboro cigarettes (table 5).

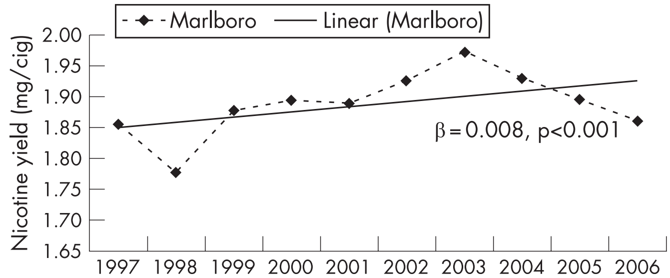

Figure 1 Trends in average nicotine yields in smoke of Marlboro brand family cigarettes. The average nicotine yields of the 18 Marlboro family brand styles that were marketed in all years between 1997 and 2006 as reported to the Massachusetts Department of Public Health (MDPH) and as reported on www.philipmorrisusa.com demonstrate a positive linear trend ($\beta = 0.008$ mg/cig/year, $p<0.001$) in multilevel mixed regression analysis controlling for brand style.

Assessment of temporal trends in nicotine yield in smoke in the Marlboro brand family

A multilevel regression analysis of the nicotine yields in smoke of the 18 Marlboro brand styles reported in each year from 1997 through 2006, as reflected by the MDPH data, shows a statistically significant increasing temporal trend of 0.008 mg/year ($p<0.001$). Average figures for nicotine yield for these Marlboro brands and the regression line showing a linear, non-random trend in nicotine yield in smoke are shown in fig 1.

DISCUSSION

The present analysis of the MDPH nicotine data confirms a statistically significant temporal trend of increased nicotine

Table 5 Multilevel mixed-effects regression analyses of trends over time in the Massachusetts regimen-measured nicotine yield in smoke, number of puffs, nicotine concentration and total nicotine yield among cigarette brand families

			LR test* brand styles	Nicotine yield in smoke (mg/cig)		Number of puffs		Nicotine (mg/g)		Nicotine (mg/cig)	
	Frequency	Brand styles	p Value	β	p Value	β	p Value	β	p Value	β	p Value
Basic	147	20	NC	0.009	0.102	–0.039	0.036	–0.045	0.195	–0.084	0.007
Benson & Hedges	29	7	0.481	–0.010	0.271	0.043	0.305	0.008	0.904	–0035	0.502
Camel	285	71	0.438	0.010	<0.001	0.074	<0.001	0.158	<0.001	0.180	<0.001
Carlton	18	8	1.000	0.005	0.740	0.052	0.514	1.300	0.038	1.619	<0.001
Doral	168	22	0.270	0.043	<0.001	0.270	<0.001	0.384	<0.001	0.445	<0.001
GPC	127	24	0.413	0.066	<0.001	0.052	0.039	–0.132	0.662	–0.050	0.364
Kool	82	25	NC	0.043	<0.001	0.018	0.591	0.132	<0.001	0.980	<0.001
Marlboro	233	39	0.287	0.015	<0.001	–0.016	0.309	0.006	0.877	–0.037	0.185
Maverick	17	3	0.460	0.047	0.003	0.131	0.007	–0.037	0.782	–0.011	0.931
Merit	25	8	0.461	0.009	0.399	0.144	0.005	0.227	0.028	0.065	0.378
Natural American Spirit	25	9	0.451	0.091	0.022	–0.062	0.770	0.024	0.897	–0.028	0.896
Newport	136	17	0.482	0.024	<0.001	0.054	<0.001	0.141	<0.001	0.134	<0.001
Parliament	19	5	0.466	–0.007	0.539	0.021	0.545	–0.007	0.952	–0.013	0.869
Salem	60	24	0.407	0.038	<0.001	0.055	0.180	0.482	<0.001	0.397	<0.001
Vantage	19	4	NC	0.011	0.438	0.163	<0.001	0.416	<0.001	0.322	<0.001
Virginia Slims	35	10	NC	0.017	0.131	0.032	0.489	–0.015	0.823	–0.031	0.516
Winston	178	31	0.425	0.007	0.144	–0.013	0.506	0.311	<0.001	0.163	<0.001

LR, likelihood ratio; NC, non-convergent (regression model).
β-coefficient of time (in years) is the predictor variable, and p values are given for all outcomes.
*LR tests are tests of the significance of the difference between brand styles within each brand family. β-coefficients are shown, with p <0.05.

yield in smoke of 0.019 mg/cig/year (1.1%) from 1997 to 2005, as measured by a smoking machine using the MA method. The increasing temporal trend was observed within all major market categories, including full flavour, light, medium, ultra-light, mentholated and non-mentholated. A similar overall temporal trend (0.029 (1.6%) mg/cig/year) was observed on exclusion of the more limited brand-specific data available in 1997.

An increase in nicotine yield in smoke from 1998 to 2005 was observed in the brands of each major manufacturer, although at varying rates. Exploratory analyses conducted on individual brand families showed increasing temporal trends in nicotine yield in smoke among Camel, Doral, Kool, Marlboro, Newport and Salem brand families, 6 of the top 10 selling brand families accounting for 63.6% of the US market share in 2005,[19] as well as GPC. Further data and research are needed to characterise the actual patterns and rates of increase in nicotine yield in smoke and their relationship with any changes in design features among individual brand families.

Design features that best defined nicotine yield in smoke in this study were concentration of nicotine in the tobacco rod, number of puffs per cigarette and per cent filter ventilation of the cigarette. Significant increases over time were observed in the concentration of nicotine (9%) and total nicotine (17%) in the tobacco rod, and in the number of puffs per cigarette (10%), whereas per cent ventilation had no significant change (from 23% to 25%) over time. Thus, the increase in nicotine yield in smoke is at least partially explained by a higher concentration of nicotine and a reduced burn rate (which increases the number of puffs generated from a given unit of tobacco). Since the total increase over time in nicotine yield in smoke was greater than that accounted for by these design factors, further influence might also be attributed to additional factors not included in this analysis.

The apparent increase in nicotine concentration within the cigarette seems to indicate manufacturers' trend towards providing greater ease in obtaining nicotine dose in a single puff. This trend is further suggested by the observed temporal increase in per puff nicotine yield in smoke. A reduced burn rate may be driving the increase in number of puffs per cigarette, which could also facilitate a greater dose of nicotine from a given cigarette in the absence of behavioural changes.

The sample of brand families and brand styles included in this analysis was defined by MDPH regulations and is not random. However, the year-to-year composition of the sample from 1998 to 2005 was consistent across market category full flavour vs light, medium or ultralight; mentholated vs non-mentholated; and filtered vs non-filtered, and does reflect the overall composition of the cigarette market. Comparison of brand styles in the initial sample with brand styles introduced in subsequent years showed no significant trend differences in nicotine yield in smoke. Comparison of candy- or exotic-flavoured brand styles, which were first introduced in 1999 and peaked in frequency in 2004, likewise showed no significant trend differences. Results when restricting the analyses to cigarette brand families with ⩾3% market share were similar to those in which the full set of available data were included. Together, these findings suggest that the trends identified in nicotine yield in smoke are neither limited to any particular market category nor driven by significant changes in the composition of the overall sample.

The MDPH issued a report in August 2006 regarding nicotine yield in smoke in US cigarettes based on data it received from tobacco manufacturers in compliance with the MA law.[20] That report observed an increase of 9.9% in the average nicotine yield in smoke of the 116 cigarette brand styles for which data were available in both 1998 and 2004.[20] PM USA issued press releases, observing that the apparent trend in nicotine yield in smoke from 1998 to 2004 was not present when data from 1997, 2005 and 2006 were included.[16] The PM USA website also shows simple linear average nicotine yields in smoke for 18 Marlboro cigarette styles reported in all years from 1997 through 2006, claiming no significant temporal trend and concluding that "year-to-year variations in nicotine occur as part of the normal processes of growing tobacco and manufacturing cigarettes".[16] The present analysis shows a significant temporal increase in nicotine yield in smoke, contradicting the PM USA claims.

Tobacco manufacturers have an extensive understanding of how design parameters affect the composition of smoke delivered to a smoker, and this understanding influences the selection and combination of these parameters as testified by a former PM scientist in the recent US District Court case.[21] The testimony described that " … a critical part of cigarette design is first ensuring that enough nicotine is available in the unsmoked rod, and then making sure that the design enables the smoker to get enough of the nicotine out to maintain his or her addiction".[21]

Further, evidence was cited that the main component of a cigarette that contributes to nicotine delivery is the tobacco blend "because the amount and types of tobacco determine how much nicotine will be in the unsmoked rod".[21 22] The testimony pointed out that year-to-year tobacco crop variation does not determine nicotine content in the cigarette, as "the manufacturers blend not only across types of tobacco but also across years, in order to compensate for the year-to-year variations…".[21]

All cigarettes are highly addictive and deadly, and relatively minor changes in nicotine yield may not significantly alter the product's addictive properties. Nevertheless, the total nicotine dosing capability, the speed with which nicotine can be delivered and the ease with which nicotine can be extracted are among the determinants of the addiction potential of a cigarette.[12] Higher nicotine content in the tobacco rod increases the potential for smokers to extract more nicotine from the cigarette. Animal and human studies have shown that the development and maintenance of a drug addiction can be facilitated by the ease in achieving addictive levels of the drug.[23]

The increase over time in nicotine yield in smoke does not necessarily signify any change in exposure within the population of smokers, particularly as smoking behaviour among humans is compensatory and will adjust for differences in smoke yield.[5] Data on market share data to compute sales-weighted measures were requested from manufacturers but were unavailable. Despite these limitations, the confirmation of a temporal trend of increased nicotine yield in smoke underscores the need for ongoing scrutiny of the cigarette market and the way that changes in design and yield may relate to population exposure and behaviour.

The Food and Drug Administration previously observed an increasing trend in nicotine yield in smoke from 1982 to 1991, with the greatest increases in the lowest-tar cigarettes.[24] This trend strongly suggested that manufacturers had manipulated and controlled the levels of nicotine.[25] More research is warranted with respect to the relationship between tar and nicotine yields during the time period (1997–2005) evaluated in the present study.

Future evaluation of product changes and their effects on exposure should include assessment of a broad combination of relevant physical and chemical design parameters (cigarette length, circumference and density; filter composition and design; ventilation; blend selection, cigarette paper composition, porosity and use of additives). Human studies, including measures of smoking topography and biomarkers of exposure,

What this paper adds

- The need to monitor trends in the nicotine content of cigarettes, the agent primarily responsible for addiction, has previously been identified. Machine-based measures of nicotine yields in smoke do not define human exposure, but may be instructive in reflecting the ease with which a smoker can extract nicotine and achieve or sustain a given level of nicotine exposure. The nicotine content of cigarettes is controlled by tobacco companies by their selection and combination of design factors. Trends in increased nicotine yield in smoke have previously been observed but not yet correlated with associated trends in specific design features.
- This comprehensive analysis of the recent 9 years of brand-specific reported nicotine yield data shows an increasing trend in nicotine yields in smoke that is associated with corresponding trends in design features, including an increasing nicotine concentration and number of puffs per cigarette.

may be necessary to predict consumer and population effects. Future regulatory strategies should therefore consider incorporating human studies as a means to evaluate exposure, as well as reporting of additional design features.

Ongoing and expanded, detailed product information disclosure is essential for the systematic monitoring of ''the changing cigarette'' urged by the 1981 US Surgeon General and others. The tobacco industry is characteristically resistant to being required to disclose information regarding its products. The industry's legal opposition to the MA nicotine disclosure reporting requirements, however, met with defeat,[26] which was one of the factors permitting the present independent examination of nicotine yield trends in relation to product design.

In conclusion, this study confirms that tobacco manufacturers have increased nicotine levels, the addictive agent of cigarettes, in the smoke of their cigarettes by increasing the nicotine in the tobacco rod and by other design modifications.

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